No. 17-290

IN THE
Supreme Court of the United States

MERCK SHARP & DOHME CORP.,
Petitioner,

v.

DORIS ALBRECHT, ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

SUPPLEMENTAL BRIEF FOR RESPONDENTS

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ARGUMENT

I. The Court's Review Is Unwarranted

The Solicitor General correctly recognizes that this case does not meet the Court's ordinary criteria for certiorari. He concedes there is no "circuit conflict" and acknowledges that allowing percolation in lower courts could "potentially 'simplify the Court's task' by refining the issue for its review." U.S. Br. 23 (alteration omitted). The Solicitor General nonetheless recommends review, while admitting (at 22) that "the question is close." Yet the Solicitor General ignores several unusual aspects of this appeal, which could hinder the Court's resolution of the legal issues presented and which render this a *sui generis* case unlikely to have a broad impact on preemption jurisprudence.

1. This case's unorthodox procedural posture could prevent the Court from reaching the question presented. In the first bellwether trial in this multidistrict litigation, the jury rejected the plaintiff's claim because she had not suffered an atypical femoral fracture. Opp. 10. The district court nonetheless issued an advisory opinion concluding that her claims were preempted. *Id.* At petitioner's urging, the court issued an order to show cause why this advisory opinion should not apply to respondents, plaintiffs in hundreds of separate cases. *Id.* Even though most plaintiffs had not yet begun discovery, the court gave respondents just 45 days to oppose preemption. *Id.* The court's process for disposing of respondents' claims was procedurally improper, as respondents argued below and in their opposition brief (at 29). This Court will confront that threshold issue if it grants certiorari. If it agrees with respondents, that would foreclose review of the merits of the district

court's preemption ruling. The Solicitor General ignores those procedural barriers to review.

2. Given this case's unusual facts, the underdeveloped record would hinder this Court's review. The FDA's Complete Response explaining its rejection of petitioner's proposed warning language focused solely on petitioner's misleading discussion of "stress fractures." It said nothing suggesting inadequate scientific evidence that Fosamax caused atypical femoral fractures. Opp. 18-19. Petitioner therefore "direct[ed] [the Third Circuit's] attention away from [the Complete Response] and instead toward a series of informal FDA communications." App. 47a.

The Solicitor General ignores petitioner's reliance on self-serving hearsay accounts of informal communications with FDA. Yet that reliance counsels against certiorari for two reasons. First, the factual record is underdeveloped. The proceedings below did not permit adequate factual development of the informal FDA communications on which petitioner relied to establish preemption. Most notably, petitioner touted a memorandum by its employee, Charlotte Merritt, recounting a telephone call with FDA, as its "single best piece of evidence." App. 49a n.125. But the abbreviated procedure deprived respondents of the opportunity to depose Merritt or otherwise test the reliability of this double hearsay document.

Second, this case is *sui generis*. Respondents are aware of no other preemption case in which the manufacturer relied on hearsay accounts of informal FDA communications to contradict the plain language of an official regulatory action. The Third Circuit's holding that factual disputes remained for the jury is thus unlikely to have significant influence beyond this case's unusual facts. As the Solicitor General

recognizes (at 23), it is "unclear whether the decision below will influence other courts."

In fact, other circuits have recently resolved preemption appeals without deciding whether the issue is a matter for the judge or jury. *See Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1103 & n.11 (10th Cir. 2017); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 721 F. App'x 580 (9th Cir. 2017). Either courts of appeals will continue avoiding this issue, making the decision below a one-off with no discernible influence on preemption jurisprudence, or courts of appeals will refine the issue by addressing it. Either way, review here is unwarranted.

3. In recommending review, the Solicitor General notes (at 22-23) that this appeal involves an MDL with hundreds of cases. But this Court's review would have limited impact on those cases.

Regardless of this Court's ruling on the question presented, respondents indisputably will be able on remand to assert failure-to-warn claims premised on petitioner's failure to warn of atypical femoral fractures in the label's Adverse Reactions section. Opp. 30. This Court's review would decide only whether respondents' failure-to-warn claims will also involve the label's Warnings and Precautions section. Opp. 30-31. The Third Circuit also held that numerous non-failure-to-warn claims (*e.g.*, design defect) were not preempted. Opp. 31. The petition did not address those claims, so they are not before the Court. The Solicitor General does not suggest otherwise. U.S. Br. 11 n.9.

If the Court wishes to review a preemption case, it should await a case where the Court's decision would dispose of at least one theory of liability.

II. The Third Circuit's Ruling Was Correct

The Third Circuit properly denied summary judgment because petitioner had not shown, beyond genuine dispute, clear evidence that FDA would have rejected a properly worded warning of atypical femoral fractures. FDA's Complete Response regarding petitioner's proposed warning rejected petitioner's focus on stress fractures but did not conclude that scientific evidence was lacking that Fosamax causes atypical femoral fractures. Opp. 16-19. Petitioner relied on hearsay accounts of informal communications with FDA to support preemption, but the Third Circuit correctly concluded that, at best, those arguments raised factual disputes that could not be resolved on an incomplete record. Opp. 20-21. The Solicitor General's attacks on the decision below rest on legal errors and mischaracterizations of the record.

1. The Solicitor General argues that this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), requiring a brand-name drug manufacturer to show "clear evidence that the FDA would not have approved a change to [a drug's] label," *id.* at 571, is always inapplicable when FDA has made a labeling decision. U.S. Br. 16-19. That argument is waived. Petitioner conceded below that the "clear evidence" standard applied, Pet'r C.A. Br. 31, and argued that it satisfied that standard, *id.* at 40-53. Moreover, no lower court has adopted the Solicitor General's limitation on *Levine*. Opp. 13-15. The Court should not grant certiorari to consider an argument that was waived below and that has never been adopted by any court.

In any event, the Solicitor General misunderstands this Court's precedents and state tort law. FDA rejection of one specific proposed warning does not necessarily establish preemption. That is because a

manufacturer must "show, by 'clear evidence,' that the FDA would have rescinded *any change* in the label and thereby demonstrate that it would in fact have been impossible to do under federal law what state law required." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 n.8 (2011) (quoting *Levine*, 555 U.S. at 571) (emphasis added). To establish liability for failure to warn under state law, a plaintiff must show that the existing "warning was insufficient," but "[t]here may . . . be[] any number of ways" for a manufacturer to meet its duty to warn. *Levine*, 555 U.S. at 565. As long as there is an adequate warning under state law that FDA would not have rescinded, compliance with state and federal law is possible.

FDA's rejection of proposed warning language may be part of a manufacturer's showing of clear evidence of impossibility, but it is not alone sufficient, nor does it excuse the manufacturer from its burden of proof. Additional factors may show that an adequate warning was possible. For example, the rejected warning might differ significantly from a warning plaintiffs contend would be adequate. *See Reckis v. Johnson & Johnson*, 28 N.E.3d 445, 459 (Mass. 2015), *cert. denied*, 136 S. Ct. 896 (2016). FDA might not have had all relevant data supporting the warning. *See Incretin-Based Therapies*, 721 F. App'x at 583-84. For injuries occurring after FDA's labeling decision, information emerging after that decision might have supported a label change. *See Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694, 701 (E.D. La. 2014). Thus, in cases involving an FDA labeling decision, courts apply the clear-evidence standard based on careful analysis of the decision and other relevant context. *See, e.g., Cerveny*, 855 F.3d at 1098-1106; *Reckis*, 28 N.E.3d at 457-60.

The Solicitor General's contention that rejection of one warning should preempt claims that petitioner should have added a different warning is emblematic of overbroad preemption theories based on "interpretation of broad federal policy objectives, legislative history, or generalized notions of congressional purposes that are not contained within the text of federal law." *Levine*, 555 U.S. at 587 (Thomas, J., concurring in the judgment).

2. The Solicitor General mischaracterizes the record. To support his preemption theory, the Solicitor General portrays (at 19-21) the Complete Response as a determination that the data were insufficient for *any* warning of atypical femoral fractures. That argument differs starkly from petitioner's theory below. Petitioner focused almost exclusively on informal communications with FDA, barely mentioning the Complete Response. Pet'r C.A. Br. 40-53. As the Third Circuit noted, petitioner "direct[ed] our attention away from [the Complete Response] and instead toward a series of informal FDA communications," App. 47a, contending that preemption was established based on communications "not disclosed in the [Complete Response]," App. 53a n.135. The Court should not grant certiorari to consider a theory not presented to the Third Circuit.

In any event, petitioner had good reason to run away from the Complete Response rather than to embrace it as the Solicitor General does: the Solicitor General's characterization of the Complete Response cannot be squared with the letter's text. The Complete Response says that FDA rejected petitioner's proposed warning because it focused on *stress fractures*, not because there was insufficient evidence that Fosamax caused *atypical femoral fractures*, the injury alleged by respondents. The Complete Response read in pertinent part:

> While the Division agrees that atypical and subtrochanteric fractures should be added to the **ADVERSE REACTIONS, Post-Marketing Experience** subsections of the FOSAMAX Tablets and Oral Solution and FOSAMAX Plus D Tablets labels, your justification for the proposed **PRECAUTIONS** section language is inadequate. Identification of "stress fractures" may not be clearly related to the atypical subtrochanteric fractures that have been reported in the literature. Discussion of the risk factors for stress fractures is not warranted and is not adequately supported by the available literature and post-marketing adverse event reporting.

C.A.App. 1500-01.

The first sentence says that petitioner's "justification" for its proposed "language" was "inadequate." The next two sentences explain why. Specifically, the "literature" did not support "[i]dentification of 'stress fractures'" in relation to atypical femoral fractures. Furthermore, "[d]iscussion of the risk factors for stress fractures" was "not adequately supported" by available literature and data.

The Complete Response shows that FDA rejected petitioner's specific language because its focus on stress fractures was not justified by atypical femoral fractures data. The Solicitor General highlights FDA's references to the literature and adverse event data to argue (at 21) that "FDA's decision . . . was based on the lack of adequate data to support a warning." But FDA said the data were inadequate to support a warning *about stress fractures*. Indeed, petitioner understood the Complete Response contemporaneously as a determination that "FDA wouldn't[] let us mention stress fractures," C.A.App. 1506, not

(as the Solicitor General contends *post hoc*) that FDA would not let petitioner warn of atypical femoral fractures.

Other evidence contradicts its position that FDA rejected *any* atypical femoral fracture warning for insufficient scientific evidence. Shortly before sending the Complete Response, FDA wrote that it wanted to "work with . . . [petitioner] to decide on language for a [Warnings and Precautions] atypical fracture language, if it is warranted." C.A.App. 1498. That message indicates that, although FDA rejected petitioner's stress fracture language, it was open to approving more appropriate warning language. That outreach would have made no sense if FDA had definitively rejected any warning. The Solicitor General ignores that document.

The Solicitor General erroneously relies (at 22) on the fact that FDA did not *require* a label change under 21 U.S.C. § 355(*o*)(4) until October 2010. The Court explained in *Levine* that Section 355(*o*)(4) did not "require[] the FDA to preapprove all changes to drug labels" and "adopted a rule of construction . . . that manufacturers remain responsible for updating their labels." 555 U.S. at 567. Although FDA repeatedly invited petitioner to "work with" it on alternative language and "resubmit" a labeling supplement, C.A.App. 1498, 1501, petitioner rebuffed those entreaties and did nothing.[1] The Third Circuit correctly

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[1] The Solicitor General notes (at 5-6, 21) FDA's practice of communicating "easily correctable deficiencies" to applicants. But the deficiencies of petitioner's proposal were not easily correctible, as *every* sentence after the first focused on stress fractures. C.A.App. 1371. The warning that FDA ultimately approved, C.A.App. 1070-71, reveals that petitioner would have needed to rewrite its proposal completely to render it adequate.

concluded that "the ball was back in [petitioner's] court to submit a revised, corrected proposal," and the record supported the inference that "it was [petitioner's] failure to re-submit a revised CBE or PAS without stress-fracture language, rather than the FDA's supposedly intransigent stance on the science, that prevented the FDA from approving a label change." App. 67a.[2]

3. The Solicitor General advocates (at 12) granting certiorari to decide whether conflict preemption under *Levine* is a matter for the judge or jury. In this case, however, summary judgment would be inappropriate under either approach because the underdeveloped record left unresolved factual disputes. That deficiency resulted from the district court's extraordinary procedural decision to decide preemption on an order to show cause rather than the more typical custom of cross-motions for summary judgment based on a fully developed record.

Respondents argued below, and still believe, that the Complete Response warrants rejection of petitioner's preemption defense as a matter of law. FDA was required to "describe all of the specific deficiencies that the agency has identified," 21 C.F.R. § 314.110(a)(1),[3] but FDA did not identify deficiencies

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[2] Even if the Complete Response reflected FDA's "determination that the data was *then insufficient* to justify . . . a warning," U.S. Br. 19 (emphasis added), that would not dispose of many respondents' claims. More than 200 respondents were injured after the May 2009 Complete Response. *See* Dist. Ct. Dkt. 2857-2. The Complete Response could not possibly prove FDA would have rejected a warning at a later date, as new scientific evidence emerged.

[3] As the Solicitor General notes (at 21), if FDA determines "that the data submitted are inadequate to support approval" of an application, FDA can issue a complete response letter

in the evidence that Fosamax causes atypical femoral fractures. Petitioner sought to contradict the official regulatory record by suggesting that FDA "gave additional reasons for the rejection, not disclosed in the [Complete Response] letter." App. 53a n.135. Petitioner's "single best piece of evidence" was Merritt's memorandum recounting a telephone conversation with FDA. App. 49a n.125; C.A.App. 1970-71. The Third Circuit recognized that deciding whether this document supported preemption required subsidiary factual determinations, including a "credibility determination" of Merritt and "determin[ing] the veracity and accuracy of the notes." App. 49a n.125. But the district court's abbreviated procedure denied respondents the opportunity to conduct discovery (*e.g.*, deposing Merritt) necessary to test petitioner's evidence.

Petitioner's theory below was that hearsay accounts of informal FDA communications established preemption; that contention raises factual disputes that preclude summary judgment regardless of whether the judge or jury is the factfinder. The Solicitor General's novel theory, that the Complete Response itself establishes preemption as a matter of law, is waived. Accordingly, the Solicitor General is incorrect (at 12) that this case "cleanly presents" the question whether preemption is decided by a judge or jury. Affirmance would be required regardless of the answer to that question.

"without first conducting required inspections and/or reviewing proposed product labeling." 21 C.F.R. § 314.110(a)(3). But this provision applies generally to applications "for drug products," not just labeling changes. 73 Fed. Reg. 39,588, 39,592 (July 10, 2008). FDA could not decide on an application seeking only a label change without reviewing the proposed labeling.

4. The Third Circuit correctly held that, when a preemption question under *Levine* raises factual disputes that cannot be resolved on summary judgment, those disputes should be submitted to the jury. Determining the applicable legal standard is a legal question. Yet resolving a preemption defense in a particular case may require finding facts and drawing inferences regarding FDA's actions. This "application-of-legal-standard-to-fact sort of question" is "commonly called a 'mixed question of law and fact.'" *United States v. Gaudin*, 515 U.S. 506, 512 (1995) (citation omitted). Such mixed questions "ha[ve] typically been resolved by juries." *Id.* In *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988), the Court held that "whether the facts establish the conditions for" a preemption defense "is a question for the jury." *Id.* at 514. The Solicitor General does not mention *Boyle* or provide any basis to distinguish it.

The Solicitor General's position that preemption is a pure legal issue stems from its incorrect view that a written FDA decision rejecting specific proposed warning language alone can establish preemption, regardless of the topics discussed in the proposed labeling or the risks faced by patients. The Solicitor General therefore analogizes (at 14-15) to *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), which held that patent construction is a legal matter for the judge. However, this analogy breaks down because "the immediate 'legal' effect of the [Complete Response] letter . . . was simply to reject [petitioner's] proposed warning. That limited determination informs but does not answer the larger question of whether the FDA would have approved a differently-worded warning." App. 53a n.135.

That larger question may involve factual disputes appropriate for a jury. This case presents a perfect example. Petitioner's reliance on Merritt's memorandum raises "precisely the types of personal evaluations and weight-of-the-evidence assessments that [courts] commit to jurors in the first instance." App. 49a n.125.

To be sure, many preemption questions turn on undisputed facts regarding FDA's official regulatory actions. Courts can resolve such cases on summary judgment. *See, e.g., Cerveny*, 855 F.3d at 1099-1106. But in unusual cases like this one, the manufacturer's preemption arguments raise factual disputes that cannot be resolved in its favor on summary judgment.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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